Standard Operating Procedure

Title: **[insert CRN name] Front Door (Local) Studies Standard Operating Procedure**	Version Number: 1	Effective Date: **12/05/2023**	Page 1 of 5

1 Purpose

This document serves to systematically capture the end-to-end process involved in the intake and management of studies entering through the [insert CRN name] Clinical Research Network (CRN) Front Door, specifically addressing local studies. From the inception of a request to the final close-out of the project, the document provides a detailed account of each stage, ensuring a comprehensive understanding of the workflow.

2 Definitions

2.1 **Local study**: A research request that has not previously been vetted by PCORnet; only using data from the [insert CRN name] (and not other PCORnet CRNs)

2.2 **DRF**: [Data Request Form Link]

2.2.1 This form will provide supporting material to understand the scope of the study. In addition to a description, the researcher will submit any deadlines or due dates for the project so that we can ensure we get the information the researcher needs in time for grants and due dates.

2.3 **P2R:** [Prep-to-Research Query Form Link]

2.3.1 Complimentary form available for external parties to submit. The [insert CRN name] Data team will receive their submission and query the [insert CRN name] database for the external party's specific research topic. Following the completion of the query, the [insert CRN name] project assignee will share the P2R Query results with the external party.

2.4 **RRPG:** Research Review and Prioritization Group.

2.4.1 This group meets every **X** week. They review all projects that researchers bring into [insert CRN name]. The committee screens and reviews projects based on [CRN] and PCORnet evaluation criteria, such as significance and rationale, approach, and patient-centeredness.

2.5 **LOS**: [Letter of Support Template]

2.5.1 A formal letter expressing support for the research project from [insert CRN name] lead, available for approved projects seeking grant funding.

2.6 **MOU**: [Memorandum of Understanding Template]

2.6.1 This document aims to offer a comprehensive elucidation of the data policies and terms of use within [insert CRN name]. It delineates specific details related to project information, data specifications, as well as the roles and responsibilities pertinent to tasks executed under the mutually established agreement between the project team and the CRN operations team.

2.7 **IRB**: [Institutional Review Board Link]

2.7.1 The IRB ensures that the rights and welfare of human subjects in research are protected.

- [IRB Resources]

2.8 **DUA**: [Data Use Agreement link]

2.8.1 The Data Use Agreement outlines the terms and conditions of data use to ensure the privacy of [insert CRN name]'s data. Any members of the research team who will use the data will sign the data use agreement.

2.9 [Platform for Data Access]

2.9.1 The [Platform for Data Access] is useful for analysis of both secure and non-secure data by research teams. [Provide any additional details as to the platform and method of extracting and providing data for researchers.]

3 Procedures

3.1 If a researcher contacts you directly to use [insert CRN name] data, direct them to the Data Request Form.

New Request

1. A researcher will submit details of a project for which they need [insert CRN name]'s data in the DRF (2.2)

1. DRF Review

    a. Assigned [insert CRN name] Ops team member will review the data request form.

i. Set up an initial phone call to discuss the specifics of the study, the needs of the researcher(s), and the project timelines.

[Call Script]

ii. Provide 1 complimentary prep-to-research query (2.3) and a feasibility assessment to maximize the potential utility of [insert CRN name] data.

[*send Data Dictionary, Query Specifications Form, and Mocked Data Sample*]

2. Review Board

Example: Research Review and Prioritization Group (RRPG) (2.4)

a. Organize a call between the RRPG, [insert CRN name] Operations members, and the PI.

b. Reach out to the PI with any questions or concerns raised by the committee. Once these questions have been resolved, the project will proceed to the next phase.

c. If the request is rejected, forward the request to the Governance Board for review.

3. [Review Board] Approval: Supporting and Regulatory Documents

a. Provide a letter of support (2.5) and any other supporting documents needed for the researcher's grant application.

b. Draft the Memorandum of Understanding (2.6) document which outlines the roles and responsibilities of [insert CRN name] in the PI's research project. Based on feedback and responses from the sponsor, the MOU can later be modified.

c. Provide support as needed while PI waits for grant approval (timeline dependent on grant approval)

Active Projects - After [insert CRN name] has approved and project is funded

Standard research study

4. IRB submission (2.7)
    a. The IRB must review and approve the project before it can start. If the project is approved by the IRB, then it moves on to the next stage.
5. Data use agreement/Memorandum of Understanding
    a. After the IRB has approved the project, finalize the Memorandum of Understanding (2.6) document and the Data Use Agreement (2.8) document with the PI.
6. [Platform for Data Access] Set-up (2.9)
    a. After all documents have been processed, the data transfer stage can begin. First, help the PI setup a data core environment.
    b. The data team will securely transfer data to the PI through the [Data Access Platform] environment.

Project Closeout

1. Dissemination
    a. Send out a survey to report any publications or presentations that have been published for the project every 6 months.
2. Project closeout
    a. Ensure that any presentation, publication, or report produced by the project team and/or using this data will acknowledge the [insert CRN name] CRN using the following statement:
        i. "This work was conducted through use of data from the [insert CRN name] Clinical Research Network and supported in-part by the Patient-Centered Outcomes Research Institute (PCORI) PCORnet grant to the [insert CRN name] Clinical Research Network (grant #)."
    b. Submit to PCORI via email [fundedpfa@pcori.org] all accepted presentations and full-length, peer-reviewed publications related to the CRN Project prior to the presentation

or publication date in good faith for a period of five years following the ("Contract Term Date")

i. Ensure that any presentation, publication, or copyright agreements concerning such accepted presentations or publications reserve adequate rights for PCORI to fully comply with its authorizing law to make the research findings available as set forth in the Contract and the PCORI Peer Review and Findings Release Process.

c. Submit reports on dissemination relating to the PCORI-funded CRN Project in good faith, annually for five years following ("Contract Term Date")